DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Chang Gung Medical Technology Co., Ltd.
% Mr. Bob Leiker
Owner
Leiker Regulatory & Quality Consulting
4157 North Del Rey Avenue
CLOVIS CA 93619

September 3, 2015

Re: K142982
Trade/Device Name: OPUS 5100 Diagnostic Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: August 6, 2015
Received: August 10, 2015

Dear Mr. Leiker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K142982

Device Name

OPUS 5100 Diagnostic Doppler Ultrasound System

Indications for Use *(Describe)*

OPUS 5100 Diagnostic Doppler Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdomen; Pediatric; Small Organ(breast, thyroid, tests); Cephalic (adult and neonatal); Trans-rectal; Trans-vaginal; Musculo-skeletal(Conventional and Superficial); Ob/GYN; Urology; Cardiac (adult and pediatric) and Peripheral Vascular.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FORM FDA 3881 (1/14)

PSC Publishing Services (301) 443-6740 EF

Diagnostic Ultrasound Indications For Use

Section 1.3 Indications for Use

510(k) Number: K142982

Device Name: OPUS 5100 Diagnostic Doppler Ultrasound System

Indications for Use:

OPUS 5100 Diagnostic Doppler Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdomen; Pediatric; Small Organ(breast, thyroid, tests); Cephalic (adult and neonatal); Trans-rectal; Trans-vaginal; Musculo-skeletal(Conventional and Superficial); Ob/GYN; Urology; Cardiac (adult and pediatric) and Peripheral Vascular.

The following transducers are intended for use with OPUS 5100 Diagnostic Doppler Ultrasound System.

Transducer model Number

LA75 Linear Array	CLA35 Curve Linear Array	MCLA65 Micro-Curved Linear array
LA75T Linear Array	CLA35R5 Curve Linear Array	PA25 Phase Array
LA75C Linear Array	CLA35C Curve Linear Array	PA25S Phase Array
LA75S Linear Array	CLA35T Curve Linear Array	PA25E8 Phase Array
LA80N Linear Array	CLA35S Curve Linear Array	PA50 Phase Array
LA85N Linear Array	TV65 Transvaginal Micro-Curved Linear array	M3D45 4D Curved Array
LA10N Linear Array	TV65S Transvaginal Micro-Curved Linear array	CGTE50 Multi-Plane Phased Array

Prescription Use__X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

510(k)_____

Diagnostic Ultrasound Indications For Use

System: Chang Gung Medical Technology Co., Ltd.
OPUS 5100 Diagnostic Doppler Ultrasound System 510(k) Submission

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	N	Note 3, 4
	Abdominal	N	N	N		N	N	Note 1	N	Note 3, 4
	Intra-operative (Specify)								N	
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N		N	N	Note 1	N	Note 3
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1	N	Note 3
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Adult Cephalic	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Trans-rectal	N	N	N		N	N	Note 1	N	Note 3
	Trans-vaginal	N	N	N		N	N	Note 1	N	Note 3
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N	Note 3
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	N	Note 3
	Other (Urology)	N	N	N		N	N	Note 1	N	Note 3, 4
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N	Note 3, 4
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	N	Note 2, 3
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	N	Note 3

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

510(k)_____

Diagnostic Ultrasound Indications For Use

Transducer: LA75 Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1	N	Note 3
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N	Note 3
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	N	Note 3
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	N	Note 3

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Office of In Vitro Diagnostic and Radiological Health

510(k)_____

Diagnostic Ultrasound Indications For Use

Transducer: LA75T Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1	N	Note 3
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N	Note 3
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	N	Note 3
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	N	Note 3

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

510(k)_____

Diagnostic Ultrasound Indications For Use

Transducer: LA75C Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1	N	Note 3
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N	Note 3
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	N	Note 3
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	N	Note 3

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

510(k)_____

Diagnostic Ultrasound Indications For Use

Transducer: LA75S Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1	N	Note 3
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N	Note 3
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	N	Note 3
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	N	Note 3

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

510(k)_____

Diagnostic Ultrasound Indications For Use

Transducer: LA80N Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1	N	Note 3
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N	Note 3
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	N	Note 3
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	N	Note 3

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

510(k)_____

Diagnostic Ultrasound Indications For Use

Transducer: LA85N Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1	N	Note 3
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N	Note 3
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	N	Note 3
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	N	Note 3

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

510(k)_____

Diagnostic Ultrasound Indications For Use

Transducer: LA10N Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1	N	Note 3
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N	Note 3
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	N	Note 3
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	N	Note 3

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

510(k)_____

Diagnostic Ultrasound Indications For Use

Transducer: CLA35 Curved Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	N	Note 3
	Abdominal	N	N	N		N	N	Note 1	N	Note 3
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	N	N	N		N	N	Note 1	N	Note 3
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N	Note 3
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

510(k)_____

Diagnostic Ultrasound Indications For Use

Transducer: CLA35R5 Curved Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	N	Note 3
	Abdominal	N	N	N		N	N	Note 1	N	Note 3
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	N	N	N		N	N	Note 1	N	Note 3
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N	Note 3
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Office of In Vitro Diagnostic and Radiological Health

510(k)_____

Diagnostic Ultrasound Indications For Use

Transducer: CLA35C Curved Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	N	Note 3
	Abdominal	N	N	N		N	N	Note 1	N	Note 3
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	N	N	N		N	N	Note 1	N	Note 3
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N	Note 3
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Office of In Vitro Diagnostic and Radiological Health

510(k)_____

Diagnostic Ultrasound Indications For Use

Transducer: CLA35T Curved Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	N	Note 3
	Abdominal	N	N	N		N	N	Note 1	N	Note 3
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	N	N	N		N	N	Note 1	N	Note 3
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N	Note 3
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Diagnostic Ultrasound Indications For Use

Transducer: CLA35S Curved Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	N	Note 3
	Abdominal	N	N	N		N	N	Note 1	N	Note 3
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	N	N	N		N	N	Note 1	N	Note 3
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N	Note 3
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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510(k)_____

Diagnostic Ultrasound Indications For Use

Transducer: TV65 Transvaginal Micro-Curved Linear Array Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal	N	N	N		N	N	Note 1	N	Note 3
	Trans-vaginal	N	N	N		N	N	Note 1	N	Note 3
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N	Note 3
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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510(k)_____

Diagnostic Ultrasound Indications For Use

Transducer: TV65S Transvaginal Micro-Curved Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal	N	N	N		N	N	Note 1	N	Note 3
	Trans-vaginal	N	N	N		N	N	Note 1	N	Note 3
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N	Note 3
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
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Diagnostic Ultrasound Indications For Use

Transducer: MCLA65 Micro-Curved Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1	N	Note 3
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
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Diagnostic Ultrasound Indications For Use

Transducer: PA25 Phased Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Adult Cephalic	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	N	Note 2, 3
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
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Diagnostic Ultrasound Indications For Use

Transducer: PA25S Phased Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Adult Cephalic	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	N	Note 2, 3
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
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Diagnostic Ultrasound Indications For Use

Transducer: PA25E8 Phased Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Adult Cephalic	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	N	Note 2, 3
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Diagnostic Ultrasound Indications For Use

Transducer: PA50 Phased Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Adult Cephalic	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	N	Note 2, 3
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
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Diagnostic Ultrasound Indications For Use

Transducer: M3D45 4D Curved Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	N	Note 3, 4
	Abdominal	N	N	N		N	N	Note 1	N	Note 3, 4
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	N	N	N		N	N	Note 1	N	Note 3, 4
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N	Note 3, 4
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
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Diagnostic Ultrasound Indications For Use

Transducer: CGTE50 Multi-Plane Phased Array Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N	Note 2, 3
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

N = new indication; P = previously cleared by FDA; E = added under this appendix

[1]: breast, thyroid, testes

Note 1: Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Power Doppler; M/Color M; B/Color Doppler/PWD and B/Power Doppler/PWD.

Note 2: TDI Note 3: 3D Note 4: 4D

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
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K142982/A001

Section 04 - 510(k) Summary

1. Date Prepared

July 07 2014.

2. Submitter

Company Name: Chang Gung Medical Technology Co., Ltd.
Head Office Address: 11F., No. 201-4, Dunhua North Rd., Songshan Dist., Taipei City 10508, Taiwan R.O.C.
Manufacturer Address: 2F., No. 118, Nanlin Rd., Taishan Dist., New Taipei City 24352, Taiwan R.O.C.
Establishment Registration Number: 3005706637
Contact: Shu Ping Tsao
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Fax: +886-2-29069797

Corresponding U.S. Agent

Contact: Bob Leiker
Leiker Regulatory & Quality Consulting
Address: 4157 North Del Rey Ave, Clovis, California 93619
Phone: (925) 719-1946
Fax: (866) 718-3819
E-mail: bobleiker@comcast.net

3. Identification of the Device

Device Name: OPUS 5100 Diagnostic Doppler Ultrasound System
Common Name: Diagnostic Ultrasound System and Transducers
Classification Name:

21 CRF892.1550 Ultrasonic Pulsed Doppler Imaging System	**Product code:** IYN
21 CRF892.1560 Ultrasonic Pulsed Echo Imaging System	**Product code:** IYO
21 CRF892.1570 Diagnostic Ultrasound Transducer	**Product code:** ITX

Classification Panel: Radiology
Device Classification: Class II
Review Category: Tier II

4. Identification of the Predicate Device

Predicate Device Name: Portable Digital Color Doppler Ultrasound System
Model: S9
Manufacturer: SonoScape Company Limited
510(k) Number: K131088

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5. Device Description

OPUS 5100 Diagnostic Doppler Ultrasound System is a compact and portable diagnostic ultrasound device, have integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

The major features of OPUS 5100 Diagnostic Doppler Ultrasound System: 128 Channel all digital beam former; progressive dynamic receive focusing; wide band all digital demodulation; native frequency digital scan converter; hand carried for portable use; remote access image management through LAN port; USB 2.0 drive for image storage and retrieving; Supports 2D B-mode (including Tissue Harmonic image, M-mode, TDI, Color Flow Doppler, Power Doppler, Pulse wave Doppler and Continuous Wave Doppler, or a combination of these modes, 3D/4D.

6. Intended Use

OPUS 5100 Diagnostic Doppler Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdomen; Pediatric; Small Organ(breast, thyroid, tests); Cephalic (adult and neonatal); Trans-rectal; Trans-vaginal; Musculo-skeletal(Conventional and Superficial); Ob/GYN; Urology; Cardiac (adult and pediatric) and Peripheral Vascular.

7. Testing

Laboratory testing was conducted to verify that the OPUS 5100 Diagnostic Doppler Ultrasound System was substantially equivalent to the Predicate Device.

8.1 IEC 60601-1: 2005 Medical Electrical Equipment – Part 1: General Requirement for Safety.

8.2 IEC 60601-1-2: 2007 Medical Electrical Equipment – Part1-2: General Requirement for Safety – Collateral Standard: Electromagnetic Compatibility – Requirement and Tests.

8.3 IEC 60601-2-37: 2008 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

8.4 NEMA UD3: 2004 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.

8.5 NEMA UD 2: 2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.

8.6 ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity.

8.7 ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization.

8. Clinical Testing

No clinical testing was required.

9. Comparison to the Predicate Device

The difference between the OPUS 5100 Diagnostic Doppler Ultrasound System and the predicate device Portable Digital Color Doppler Ultrasound System, Model S9 in almost every part are listed in the table below.

Table 1 Substantial Equivalent Comparison Table

Items	Proposed Device	Predicate Device
General		
Device Name	OPUS 5100 Diagnostic Doppler Ultrasound System	Portable Digital Color Doppler Ultrasound System, Model S9
Intended Use	The OPUS 5100 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdomen; Pediatric; Small Organ(breast, thyroid, tests); Cephalic (adult and neonatal); Trans-rectal; Trans-vaginal; Musculo-skeletal(Conventional and Superficial); Ob/GYN; Urology; Cardiac (adult and pediatric) and Peripheral Vascular.	The SonoScape S9 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.
Classification Name	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer
Product Code	90-IYN/90-IYO/90-ITX	90-IYN/90-IYO/90-ITX
Regulation Number	892.1550/892.1560/892.1570	892.1550/892.1560/892.1570
Panel	Radiology	Radiology
Class	II	II
Specification		
Transducer Types & Connectors	LA75 Linear array LA75T Linear array LA75C Linear array LA75S Linear array LA80N Linear array LA85N Linear array LA10N Linear array	L741 Linear array L742 Linear array L752 Linear array

Items	Proposed Device	Predicate Device
	CLA35 Curved Array CLA35R5 Curved Array CLA35C Curved Array CLA35T Curved Array CLA35S Curved Array	C344 Curved Array C322 Curved Array C353 Curved Array
	TV65 Transvaginal Micro-Curved Array TV65S Transvaginal Micro-Curved Array	6V1 Micro-Curved Array 6V3 Micro-Curved Array
	MCLA65 Micro-Curved Array	/
	PA25 Phased Array PA25S Phased Array PA25E8 Phased Array PA50 Phased Array	2P2 Phased Array 3P1 Phased Array 5P2 Phased Array 8P1 Phased Array
	4D Curved Array: M3D45 - 4.5 MHz	VC6-2 Curved Array
	CGTE50 Multi-Plane Phased Array	/
	Multi-port connector connects 2 transducers.	Multi-port connector connects 2 transducers.
Design	Based on an embedded Linux operating system. Based on 128 channel full digital beam former. Autocorrelation for color processing and FFT for pulse and CW Doppler processing. Supporting Linear, Curve linear and Phase array probes from 2 to 14 MHz. Cine play back capability and Image file archive. Software upgrade with USB flash drive. Digital Scan Converter 800x600.	Based on an embedded Linux operating system. Based on 128 channel full digital beam former. Autocorrelation for color processing and FFT for pulse and CW Doppler processing. Supporting Linear, Curve linear and Phase array probes from 2 to 15 MHz. Cine play back capability and Image file archive. Software upgrade with USB flash drive. Digital Scan Converter 800x600.
Patient Contact Materials	RVT664+ Ultrason S2010 silicon rubber complies with ISO 10993-5.	RVT664+ Ultrason S2010 silicon rubber complies with ISO 10993-5.
Operation Mode	B, M, CFM, CPA, PW, CW, THI, TDI 3D/4D Mode, Color M Mode and combine mode.	B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image, 3D/4D Mode, Color M Mode
Display Mode	Single and dual 2-D; Display of Duplex 2 D/M-mode; 2-D/Pulsed Doppler and Triplex 2-D/CD/Pulsed Doppler image formats; Dual B and	Dual B, Quad Display, B and M, B and Doppler, B+Color, Dual B(Flow), Triplex mode; B, CFM, and PW/CW; B, DPI, and PW/CW; B, THI and

Items	Proposed Device	Predicate Device
	Color in real time.	Color M, steer M, Dual B and Color in real time, Compound imaging, Panoramic Imaging, Trapezoid Imaging.
Display Monitor	15" LCD color monitor.	15" Widescreen LCD monitor.
Measurement	Distance; Area; Circumference; Calipers; Volume; Velocity; HR, PI, RI, Cardiac, OB/GYN, Urology, Vascular and small part package.	Distance; Area; Circumference; Calipers; Volume; Velocity; HR, PI, RI, Cardiac, OB/GYN, Urology, Vascular and small part package.
Users / Sites	Hospitals, clinics usage.	Hospitals, clinics usage.
Acoustic Output	Track 3: MI, TIS, TIC, TIB Derated Ispta: 720 mW/cm^2 (max.) TIS/TIB/TIC: 0.2 ~ 4.0 (Range) Mechanical Index: 1.9 (max.) Derated Isppa: 190 W/cm^2 (max.)	Track 3: MI, TIS, TIC, TIB Derated Ispta: 720 mW/cm^2 (max.) TIS/TIB/TIC: 6.0 (max.) Mechanical Index: 1.9 (max.) Derated Isppa: 190 W/cm^2 (max.)
Labeling	Operator's Manual, brochure.	Operator's Manual, brochure.
Power Requirement	Power requirement: 100 Volts AC, 1.84 Amps 120 Volts AC, 1.56 Amps 230 Volts AC, 0.81 Amps 250 Volts AC, 0.74 Amps Power consumption: 130 watts max.	Power requirement: Voltage: 110-240 VAC Frequency: 50/60 Hz Power consumption: 110-240VAC, 2.7-1.2A
Operating Condition	Temperature: 5 □ ~ 40 □. Relative humidity: 10 ~ 80%. Air pressure: 700 hPa ~ 1060 hPa.	Temperature: 10 □ ~ 40 □. Relative humidity: 30 ~ 75%. Air pressure: 700 hPa ~ 1060 hPa.
Storage Condition	Temperature: -25 □ ~ 55 □. Relative humidity: 10 ~ 90%. Air pressure: 700 hPa ~ 1060 hPa.	Temperature: -20 □ ~ 55 □. Relative humidity: 20 ~ 90%. Air pressure: 700 hPa ~ 1060 hPa.
Safety Test Items		
Electronic Safety	IEC 60601-1	IEC 60601-1
Electromagnetic Compatibility	IEC 60601-2	IEC 60601-2
Performance	IEC 60601-2-37	IEC 60601-2-37
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10
Level of Concern of Software	Moderate level of concern system	Moderate level of concern system

10. Conclusion

There are some differences between the proposed device and predicate device. All the parameters comply with 21CFR1020.33 and related IEC standards, so those differences between proposed device and predicate device do not affect the safety and effectiveness.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, it can be concluded that OPUS 5100 Diagnostic Doppler Ultrasound System is substantially equivalent to the predicate device with regard to safety and effectiveness.